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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/803, 954 02/21/97 LANGLEY

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18N2/1208

EXAMINER

HAYES, R

ART UNIT

PAPER NUMBER

1817 *H*

DATE MAILED:

12/08/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

See the attached!

Office Action Summary

Application No.	08/1803954	Applicant(s)	Langley et al.
Examiner	Hayes	Group Art Unit	1817

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 30 ^{days} MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- Responsive to communication(s) filed on _____.
- This action is **FINAL**.
- Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

Claim(s) 1-11, 28-29, 31-32, 34, 37-39 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

Claim(s) 1-11, 28-29, 31-32, 34, 37-39 are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - All Some* None of the CERTIFIED copies of the priority documents have been received.
 - received in Application No. (Series Code/Serial Number) _____.
 - received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Notice of References Cited, PTO-892
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Interview Summary, PTO-413
- Notice of Informal Patent Application, PTO-152
- Other _____

Office Action Summary

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-11, 28-29, 31-32 & 37, drawn to polypeptides having metalloproteinase inhibitor activity, and pharmaceutical compositions thereof, classified in class 514, subclass 2.
 - II. Claim 34, drawn to a method of treating rheumatoid arthritis comprising administering an effective amount of a metalloproteinase inhibitor, classified in Class 514, subclass 12.
 - III. Claims 38-39, drawn to antibodies to a polypeptide having metalloproteinase inhibitor activity, classified in Class 530, subclass 387.1.
2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper, because these products appear to constitute patentably distinct inventions for the following reasons:

Groups I-II are directed to products that are physically and functionally distinct; involving proteins and antibodies. Each of these products can be prepared by different processes, such as though chemical synthesis or isolation from natural sources using various isolation/purification

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procedures. For example, although the antibodies of Group III can be used in isolating the proteins of Group I, the antibodies of Group III can be generated by immunizing animals with a small synthetic portion of the full length protein, and can be used diagnostically in other ways, such as in affinity chromatography or in immunoassays, or as therapeutic agents themselves. The proteins of Group I can be utilized in making the antibodies of Group III, but not vice versa. It is pointed out that there is a proper distinction between these groups, since each product is not required in order for the other to exist. Thereby, these groups are distinct and separable for the reasons stated.

Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins of Group I can be used in other materially different methods, such as in affinity chromatography to isolate co-factors or receptor molecules. The method of treating patients with polypeptides having metalloproteinase inhibitor activity requires cells in a patient to treat, which are not required for Group III.

It is noted that the method of Group II does not require the product of Group III, and vice versa.

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3. Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

4. A clean copy of the claims is further requested to prevent future potential problems, because instant pages 100-105 were canceled by amendment D in the parent application.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

RC

Robert C. Hayes, Ph.D.
December 5, 1997

AC

**ANTHONY C. CAPUTA
PRIMARY EXAMINER
GROUP 1800**